UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

"Track 3 Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

DEFENDANTS' JOINT MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(B) AND MEMORANDUM OF LAW IN SUPPORT

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INTRODUCTION

Defendants dispute the legal framework set out in this Court's ruling on Defendants' motion to dismiss. But even under that framework, Plaintiffs failed at trial to prove that any Defendant committed acts that could have supported a jury finding of nuisance liability. At most, Plaintiffs questioned whether Defendants failed to comply with what Plaintiffs' experts would consider pharmacy "best practices." At closing argument, Plaintiffs argued to the jury that Defendants should be held liable for not following the optimal "standard of care" and for not being "the leaders out there" in the market. Dkt. 4153 at 7105, 7116 (Nov. 15 trial tr., vol. 28). But even if Plaintiffs and their hired experts were right about such "best practices" (and they are not), a failure to comply with a standard of care, without more, can establish only an actor's *negligence*. Under Ohio law, though, negligence can establish a claim only for *qualified nuisance*. An *absolute nuisance*, by contrast, requires proof of either unlawful conduct or intentional and culpable conduct. Plaintiffs press only absolute nuisance, and they have not presented legally sufficient evidence of either unlawful or intentional and culpable conduct. Nor have they introduced evidence from which a reasonable jury could have concluded that any Defendant was a proximate cause of an ongoing nuisance. Judgment as a matter of law is therefore necessary.

Plaintiffs' public nuisance claim is legally deficient for many reasons that do not depend on the evidence offered at trial. Plaintiffs seek billions of dollars in so-called "public nuisance" liability for alleged harms caused by end-users' own misuse of otherwise lawful products. As many courts have recognized, such an unprecedented expansion of state nuisance law to lawful products would swallow whole the carefully calibrated law of products liability. *See, e.g.*, *Tioga Pub. Sch. Dist. No. 15 of Williams Cnty. v. U.S. Gypsum Co*., 984 F.2d 915, 921 (8th Cir. 1993) (stating that if courts were to recognize products-based nuisance claims, "[n]uisance . . . would become a monster that would devour in one gulp the entire law of tort").

In any case, the Controlled Substances Act ("CSA") duties Plaintiffs allege that Defendants breached do not actually exist and are precluded by Ohio nuisance law. And the proper party to enforce any CSA requirements is the United States Drug Enforcement Administration ("DEA") or the Ohio Board of Pharmacy, not two political subdivisions whose built-for-litigation theories will only disrupt the doctor-patient relationship to the detriment of patient health. Recognizing that the Court has rejected these arguments, Defendants restate them in the second half of their brief for preservation purposes.

LEGAL STANDARD

"Under Rule 50, a court should render judgment as a matter of law when 'a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.'" *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 149 (2000). "[T]he standard for granting . . . judgment as a matter of law . . . is the same" as for granting summary judgment. *Id.* at 150 (quotation marks omitted).

"If the court does not grant a motion for judgment as a matter of law made under Rule 50(a) . . . the movant may file a renewed motion for judgment as a matter of law." Fed. R. Civ. P. 50(b). "A Rule 50(b) motion is only a renewal of the preverdict motion, and it can be granted only on grounds advanced in the preverdict motion." *Hanover Am. Ins. Co. v. Tattooed Millionaire Ent., LLC*, 974 F.3d 767, 780 (6th Cir. 2020) (quotation marks omitted). Defendants filed Rule 50(a) motions on October 29, 2021, and renew the same arguments here and in their individual Rule 50(b) motions. *See* Dkt. 4098 (Defendants); Dkt. 4100 (Walmart); Dkt. 4102 (Walgreens); Dkt. 4103 (CVS).

ARGUMENT

I. EVEN UNDER PLAINTIFFS' AND THE COURT'S VIEW OF THE LAW, DEFENDANTS CANNOT BE HELD LIABLE FOR AN ABSOLUTE PUBLIC NUISANCE.

In Ohio, a public nuisance can be either absolute or qualified: A qualified nuisance depends on proof of negligence, while an absolute nuisance requires proof of either unlawful conduct or intentional and culpable conduct. *See, e.g.*, *Barnett v. Carr ex rel. Est. of Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001); Black's Law Dictionary (11th ed. 2019) (defining "culpable" as "[g]uilty," "blameworthy," or "[i]nvolving the breach of a duty"). Plaintiffs eschewed any qualified nuisance claim, instead raising a claim only under the absolute nuisance doctrine. Because there is "no legally sufficient evidentiary basis" for a reasonable jury to find that Defendants acted either (1) unlawfully or (2) intentionally and culpably, the Court should enter judgment for Defendants, even under Plaintiffs' view of the law and this Court's earlier decisions. *Reeves*, 530 U.S. at 149.

A. No Reasonable Juror Could Have Found That Defendants Engaged in Unlawful Dispensing Conduct.

Plaintiffs did not present legally sufficient evidence of unlawful dispensing conduct by any Defendant. Any dispensing duties imposed on Defendants must derive from the CSA's text or its regulations. There was no evidence introduced at trial that showed Defendants' pharmacists in Lake and Trumbull Counties knowingly dispensed a single illegitimate opioid prescription in violation of 21 C.F.R. § 1306.04(a). And no one disputes that Defendants complied with the physical security and recordkeeping requirements expressly provided by those sources of law. That resolves any question of whether Defendants' dispensing practices were unlawful.

At the motion-to-dismiss stage, however, this Court held that Defendants are subject to additional dispensing-related duties at the corporate level, including "an affirmative obligation to

protect not only against diversion via theft but also other forms of diversion more broadly." *See* Dkt. 3403 at 25; Dkt. 3499 at 15. Defendants maintain their objections to that ruling. *See, e.g.*, Dkt. 3439 (Pharmacy Defendants' Motion for Reconsideration or Certification of Order Denying Motion to Dismiss). Even assuming the law actually does impose those additional requirements, however, Plaintiffs did not introduce evidence that any Defendant violated them.

Under the Court's holding, which (again) Defendants object to, Plaintiffs must show that Defendants acted with "deliberate ignorance" or "willful blindness," not merely recklessly or negligently. Dkt. 3499 at 7. To be "willfully blind," a defendant must have taken "deliberate actions to avoid confirming a high probability of wrongdoing." *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011) (citing G. Williams, Criminal Law § 57, at 159 (2d ed. 1961)); *see also* Black's Law Dictionary ("Deliberate avoidance of knowledge."). The defendant must have for all practical purposes "actually known the critical facts"—by "subjectively believ[ing] that there is a high probability that a fact exists" and by taking "deliberate actions to avoid learning of that fact." *Glob.-Tech Appliances*, 563 U.S. at 769. To clear this hurdle, Plaintiffs were required to present evidence that each Defendant (1) subjectively believed its pharmacists were violating the CSA and (2) intentionally took actions to avoid learning about it. *See id.*

Plaintiffs attempted to prove willful blindness in three principal ways, but none finds any basis in the CSA, and none is remotely sufficient to show that any Defendant acted with willful blindness:

First, Plaintiffs leveraged the volume of Defendants' dispensing activity alone, alleging that Defendants dispensed "massive amounts of prescription opioids into the Counties." Dkt. 4131 at 19, 23, 37, 47.

Second, Plaintiffs faulted Defendants for not analyzing and adequately sharing prescription data with their pharmacists. *See, e.g.*, Dkt. 4131 at 20, 31, 41 (Plaintiffs arguing that Defendants have acted unlawfully by not "utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion as well as to recognize and resolve red flags"); Dkt. 4005 at 1048–49 (Oct. 7 trial tr., vol. 4) (stating Carmen Catizone's Opinion 13 as "[e]ach defendant failed to provide its pharmacists with data, information and the tools necessary to assist the pharmacists in fulfilling their corresponding responsibility duties, including but not limited to utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion, as well to recognize and resolve red flags").

Third, Plaintiffs argued that Defendants were responsible for not informing their pharmacists of certain "red flags" Plaintiffs' expert has specified and for their pharmacists not documenting the resolution of such red flags. *See, e.g.*, Dkt. 4131 at 20, 31, 41 (Plaintiffs arguing that Defendants have acted unlawfully by failing to "accurately identify and document all red flags raised by the prescription, patient, and prescriber" and "document[] the resolution of red-flagged prescriptions"); Dkt. 4005 at 1006 (Oct. 7 trial tr., vol. 4) (stating Catizone's Opinion 10 as "[e]ach defendants' local stores filled thousands of prescriptions presenting red flags without evidence of resolving those red flags").

Volume. Defendants cannot as a matter of law be held liable simply for dispensing opioid medications in large volumes. It is uncontroverted that Defendants only ever dispensed opioid medications approved by the U.S. Food and Drug Administration (FDA). *See, e.g.*, Dkt. 4005 at 796 (Lembke testimony, Oct. 7 trial tr., vol. 4); Dkt. 4023 at 1723 (Rannazzisi testimony, Oct. 13 trial tr., vol. 7); Dkt. 4090 at 4153 (Dr. Keyes testimony, Oct. 26 trial tr., vol. 16). The FDA determined that the "benefits of the drugs outweigh its risks," that the drugs are "safe and

effective[,]" and that the drugs are "effective to treat" a patient's medical condition. Dkt. 4093 at 4424 (Toiga testimony, Oct. 27 trial tr., vol. 17); *see also* 21 C.F.R. § 314.125 (listing grounds for denial of new drug application including that the drug will not "have the effect it purports or is represented to have" or "is unsafe for use under the conditions prescribed"); 21 U.S.C. § 355.

It is uncontroverted that DEA regulated the volume of prescription opioids by setting quotas on the amount of prescription opioid medications that could be manufactured each year. Dkt. 4023 at 1725-26 (Rannazzisi testimony, Oct. 13, 2021 trial tr., vol. 7). Those quotas were designed to "meet the legitimate medical demands without providing excess medication that may be diverted into the illicit market." *Id.* at 1727. It also is uncontroverted that pharmacies may dispense a prescription opioid medication only when presented with a prescription written by a doctor or other medical practitioner, and there is no evidence that Defendants' pharmacists dispensed a prescription opioid medication in the absence of a prescription.

In contravention of the Supremacy Clause, Plaintiffs seek to use Ohio nuisance law to override Congress and FDA's determination that opioid medications may be lawfully prescribed and dispensed. *See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (state common-law rules are preempted if they "actually conflict[] with federal law," including when compliance with both federal and state standards are a "physical impossibility" (quotation marks omitted)). Plaintiffs thus must point to something else besides the mere fact that Defendants dispensed FDA-approved medications pursuant to legitimate prescriptions written by doctors—no matter how big or how small Defendants' overall volume of dispensing might be. Moreover, it is permissible under the law for pharmacies to fill large numbers of legitimate opioid prescriptions. There are no volume restrictions on the opioid prescriptions that a pharmacy or pharmacist may

fill. Therefore, Defendants may not be held liable simply for filling large volumes of opioid prescriptions.

Data-Analysis and Sharing. The Court has already ruled that the CSA does not require any data to be shared among a chain's individual pharmacists, explaining that "there is no absolute requirement . . . that a pharmacy must conduct a computerized [] analysis of each prescription before filling it." Dkt. 3499 at 7. At trial, Defendants' DEA expert, Robert Hill, confirmed that the CSA and DEA regulations do not require "doctor monitoring programs" generally, "data programs to review and block doctors," or the use of "algorithms to monitor their dispensing"—and that the DEA has never provided any official guidance to that effect. Dkt. 4124 at 6436–37 (Nov. 5 trial tr., vol. 24).

Regardless, Defendants *did* share data about prescriptions across all pharmacies. They did it through their patient-profile systems and through Ohio's prescription drug monitoring program, OARRS (Ohio Automated Rx Reporting System), which tracks the dispensing of controlled prescription drugs statewide, and other Defendant-specific proprietary programs. *See* Dkt. 4111 at 5367 (Nov. 2 trial tr., vol. 21) (Ohio Board of Pharmacy Agent Trey Edwards agreeing that "since a CVS and a Walgreens and a Walmart are filling prescriptions, they are providing information that goes into the OARRS database"); Dkt. 4008 at 1159–60 (Oct. 8 trial tr., vol. 5); Dkt. 4115 at 5676-5679 (Nov. 3 trial tr., vol. 22).

Plaintiffs' argument that Defendants' systems could have been more advanced in no way suggests that any Defendant took "deliberate actions to avoid confirming a high probability of wrongdoing," as required to establish willful blindness. *Glob.-Tech Appliances*, 563 U.S. at 769. Plaintiffs' second-guessing about "best practices" is at most a negligence theory; it certainly does not show knowledge.

Red Flags and Documentation. Plaintiffs assert that Defendants were willfully blind because they did not instruct their pharmacists about the 16 "red flags" Plaintiffs' expert identified and because their pharmacists did not document the resolution of such red flags.

Neither the CSA nor its Ohio analog comes close to supporting this deeply flawed approach. The phrase "red flags" itself does not appear anywhere in the CSA, any DEA regulation, or any analogous Ohio law or regulation. More importantly, those sources of law do not contain any list of specific indicators, much less the 16 specific "red flags" listed by Plaintiffs' expert, or suggest that any such list should be rigidly followed. *See* Dkt. 4008 at 1228 (Nov. 3 trial tr., vol. 22). They do not require corporate or other policies of any sort. Nor do they contain any mandate to document the resolution of those indicators. So the mere fact that an individual pharmacist might not have fully documented how he or she resolved a "red flag," in the eyes of an expert witness analyzing data entries years after the fact, says nothing about the pharmacist's mental state at the time of dispensing. Across the board, Plaintiffs' dispensing theory lacks a legal foundation and therefore cannot be the basis of a jury verdict.

Again, Hill testified at trial that it is not necessary for a pharmacy to have a written policy identifying every conceivable red flag, that DEA regulations do not "require the implementation of red flag computer alerts," and that DEA has never "provided official guidance to pharmacies indicating that they should implement red flag alerts in their computer systems." Dkt. 4124 at 6433, 6436 (Nov. 5 trial tr., vol. 24). He also explained that neither the CSA nor its regulations "even discuss[es] the documentation of red flags," let alone requires it, and that DEA has never sent a "Dear Registrant" letter requiring documentation. *Id.* at 6433–35. Likewise, Ohio Board of Pharmacy Agent Trey Edwards agreed that documentation was not required by law. Dkt. 4111 at 5467 (Nov. 2 trial tr., vol. 21).

Plaintiff's expert, Carmen Catizone, testified that these responsibilities emanated from the "customary scope of pharmacy practice"—a dubious proposition in and of itself. Dkt. 4005 at 1040 (Oct. 7 trial tr., vol. 4). At trial, he could not identify even a single pharmacy anywhere in the world that actually follows the method he proposed, explaining that he never bothered to study the matter. *See* Dkt. 4008 at 1241–42 (Oct. 8 trial tr., vol. 5). Simply put, a practice that not one pharmacy follows cannot be considered "customary." *Custom*, Black's Law Dictionary (a practice defined by "common adoption and long, unvarying habit"). Customs also change over time, and it has been over 20 years since Catizone was last a dispensing pharmacist. *See* Dkt. 4017 at 1353–54 (Oct. 12 trial tr., vol. 6).

It is little surprise that pharmacies have not adopted Plaintiffs' red-flag protocol. Defendants' clinical expert, Dr. Robert Wailes, testified that applying red flags in a "mechanical" and "absolute" manner was "problematic," because it overrides the "pharmacists' judgment in whether to fill a prescription or not[,]" and thus would "significantly interfere with legitimate patient care and safety." Dkt. 4107 at 4783, 4816 (Oct. 29 trial tr., vol. 19); *see also* Dkt. 4093 at 4453 (Oct. 27 trial tr., vol. 17) (FDA official Theresa Toiga testifying that the "FDA has been very reluctant to put hard limits on opioids because of the fear that it would unduly restrict the individualized treatment of patients who may need opioids to treat their pain"). The "mechanistic rigidity" of such scheme ignores that the physician, not the pharmacist, is best positioned to determine the appropriate care for a patient, given that it is "the physician who has all the information, they have the history, the physical, the background, the labs, the experience, and all the information that it takes to make a medical decision." Dkt. 4107 at 4798 (Oct. 29 trial tr., vol. 19); Dkt. 4106 at 4744–45 (Oct. 28 trial tr., vol. 18).

Plaintiffs' indicators are also "overbroad" because they "capture a host of prescribing circumstances that fall well within the medical standard of care," including cancer care and end-of-life care. Dkt. 4107 at 4783, 4815 (Oct. 29 trial tr., vol. 19). In fact, Plaintiffs' flags would alert 19.4%, or about 1 out of 5, of prescriptions. *Id.* at 4783. And, just taking CVS as an example, Plaintiffs' methodology flagged 37% of the prescribers who wrote prescriptions that were filled by CVS pharmacies in Lake and Trumbull Counties. CVS-MDL-04343a. That result makes little sense given DEA testimony that over 99% of prescribers appropriately prescribed opioid medications. Dkt. 4023 at 1781 (Oct. 13 trial tr., vol. 13); *see also* Dkt. 4118 at 6111 (Nov. 4 trial tr., vol. 23) (CVS data expert Dr. William Choi testifying that these statistics were "not reconciling"); Dkt. 4111 at 5470 (Nov. 2 trial tr., vol. 21) (Edwards testifying that the "vast majority of doctors are writing controlled substances prescriptions legitimately"). Such an overly sensitive screen would inevitably lead to "alert fatigue" because "[i]if there [are] too many alerts, then you don't pay much attention" to them, Defendants' clinical expert Dr. Wailes explained. Dkt. 4107 at 4986 (Oct. 29 trial tr., vol. 19).

Plaintiffs' focus on *documentation*, rather than the red flags themselves, fares no better. Although the ground for any such argument was not well articulated at trial, Plaintiffs alluded to several sources of law for their claim that Defendants' pharmacists were required to *document* the resolution of red flags, but none imposes such a duty:

First, Plaintiffs cite 21 C.F.R. § 1306.04(a), which forbids "knowingly filling" an invalid prescription. That regulation says nothing about documenting the resolution of red flags. Dkt. 4023 at 1773–74 (Oct. 13 trial tr., vol. 7) (Rannazzisi testifying that he was not aware of any statute, regulation, or DEA-published document during his tenure at DEA that required a

pharmacist to document the resolution of red flags). And the absence of documentation of the resolution of red flags is not evidence of knowledge (or willful blindness).

As Agent Edwards explained, documentation is not required by law, and a pharmacist "could do the hard work and the careful work to resolve a red flag but not write down what she or he did." Dkt. 4111 at 5467–68 (Nov. 2 trial tr., vol. 21). Hill similarly testified that pharmacists could resolve red flags without documenting that resolution. Dkt. 4124 at 6438 (Nov. 5 trial tr., vol. 24). Even Plaintiffs do not contend that failing to document the investigation of every prescription written by a doctor outside of a 25-mile radius, for example, constitutes willful blindness, and no evidence suggests otherwise. *See, e.g.*, Dkt. 4008 at 1244–45 (Oct. 8, trial tr., vol. 5).

The same holds true for Ohio law. Although pharmacists must "us[e] [their] professional judgment" to "take appropriate steps to avoid" problems including abuse, misuse, drug interactions, and allergies, there is no rigid list of "flags" that triggers a duty not to fill. As Agent Edwards testified, there also is no associated documentation requirement. Ohio Admin. Code § 4729-5-20(A). Most importantly, unwittingly failing to follow the "best practices" opinions crafted after the fact by Plaintiffs' expert witness would at most support a claim of negligence. That is no help to Plaintiffs, however, because negligence is cognizable only in a qualified nuisance claim—and Plaintiffs make no such claim here. *Carr*, 2001 WL 1078980, at *10–11.

Second, 21 U.S.C. § 827(a) does not provide the support for a "red flag" documentation requirement. That provision requires every registrant to "maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him[.]" No one disputes that Defendants did exactly that. Instead, the dispute here

concerns whether the CSA requires the documentation of the *resolution of suspicions*, not documentation of drugs dispensed. The regulation requires no such thing.

Third, Plaintiffs invoked a pair of agency adjudications: *Paul H. Volkman*; *Denial of Application*, 73 Fed. Reg. 30,630-02 (May 28, 2008), and *Hills Pharmacy, LLC*; *Decision and Order*, 81 Fed. Reg. 49,816 (July 28, 2016). In *Volkman*, DEA suspended the registration of a physician who kept no record of the drugs he prescribed for an entire year and generally exhibited "wholly deficient recordkeeping." 73 Fed. Reg. at 30,644. Likewise, the pharmacy in *Hills Pharmacy* "failed to complete a biennial inventory," note the date and quantity it received of schedule II drugs, or keep its records "readily retrievable." 81 Fed. Reg. at 49,816. Nobody contends that any Defendant here failed to keep complete and accurate logs of all medications they dispensed. Thus, these agency adjudications have nothing to do with this lawsuit.

In sum, Plaintiffs' novel "red flags" provide no basis for believing any pharmacist actually harbored any suspicions at the time of dispensing a particular prescription, and their documentation rules are at most based on their expert's opinion about what constitutes "best practices"; they find no basis in the CSA or its regulations. That Defendants did not adopt Plaintiffs' model is not evidence of willful blindness. Thus, under this Court's rulings, which, again, Defendants object to, judgment must be granted for Defendants on their dispensing conduct.

B. No Reasonable Juror Could Have Found That Defendants Engaged in Intentional, Culpable Conduct.

Plaintiffs also failed to prove that Defendants engaged in intentional and culpable conduct independent of any violation of the CSA and thus no reasonable juror could have found this element of the public nuisance test.

At closing, Plaintiffs argued that the "intentional element" of the public nuisance test was satisfied because Defendants "weren't accidently dispensing opiates" like when "someone

accidently dump[s] a bunch of lead into the water supply without realizing" it. Dkt. 4153 at 7169 (Nov. 15 trial tr., vol. 28). In other words, Plaintiffs' sole argument under the intentional prong was that Defendants *intentionally dispensed* opioid medications. But it was decidedly *not* enough for Plaintiffs to show that Defendants intended to dispense. Instead, they had to show that Defendants acted "with the purpose to produce a specific result"—namely, an interference with public health or safety resulting from the oversupply and diversion of prescription opioids in Lake and Trumbull Counties. Non-accidental dispensing is not (and cannot be) enough.

Nor would it be permissible for Plaintiffs to rely on intentional but *lawful* conduct. Penalizing Defendants for dispensing conduct—whether intentional or not—that Congress considered and allowed under the CSA is clearly preempted by federal law. Such theory of liability would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Arizona v. United States*, 567 U.S. 387, 399–400 (2012), because it would "skew[]" the "delicate balance of statutory objectives" set by the Act: ensuring the availability of medically indicated therapeutics while, at the same time, limiting the improper use of controlled substances. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Ohio public nuisance law itself forbids such second-guessing of federal policy. A nuisance is an unreasonable interference with a public right. Under Ohio law, an interference with a public right is "unreasonable" only if Plaintiffs prove that the gravity of their harm outweighs the utility of Defendants' conduct, which involves evaluating the "social value" of such conduct. 1 Ohio Jury Instructions CV 621.05(4), (6). Congress and the FDA have already considered the dispensing conduct permitted by the CSA and determined that the social utility of the conduct outweighs the risk of harm. *See* Dkt. 4093 at 4424–26 (Oct. 27 trial tr., vol. 17) (Toiga testifying that FDA approves drugs only if "the benefits of the drug[] outweighs its risks" even after

accounting for, among other things, the "risks for public health" and "risks that come from inappropriate use of the drug"). Conduct that is fairly encompassed within the scope of the CSA, and permitted by it, thus cannot be "unreasonable" as a matter of Ohio law. *Cf. State v. Purdue Pharma L.P.*, No. 30-2014-00725287, at 14 (Cal. Super. Ct. Orange Cnty. Nov. 1, 2021) (explaining that "as the Federal government and the California legislature have already determined . . . the social utility of medically appropriate prescriptions outweighs the gravity of harm inflicted by them and so is not 'unreasonable' or, therefore, enjoinable").

For this reason, no "actionable" claim for public nuisance lies where "a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct exist." *Brown v. Cnty. Comm'rs. of Scioto Cnty.*, 622 N.E.2d 1153, 1158–60 (Ohio Ct. App. 1993). Thus, duly licensed individuals who engage in extensively regulated activities cannot be held liable for absolute public nuisance. *State ex rel. Schoener v. Bd. of Cnty. Comm'rs of Hamilton Cnty.*, 619 N.E.2d 2, 6 (Ohio Ct. App. 1992) (dismissing the absolute public nuisance claim and noting that "we think it [is] fair to say in law that part of the *quid pro quo* for the submission to such exacting regulatory oversight is the operator's insulation from liability under a theory of strict liability").

Because Plaintiffs did not prove that Defendants engaged in any *unlawful* dispensing conduct, because Plaintiffs did not demonstrate that Defendants engaged in any intentional conduct beyond intending to dispense FDA-approved opioid medications, and because intentional but lawful dispensing conduct cannot form the basis for absolute nuisance liability, Defendants are entitled to judgment as a matter of law. At minimum, however, Defendants are entitled to a new trial (as argued alternatively via separate motion): The jury verdict form did not distinguish between unlawful and intentional conduct and thus the jury's verdict could well have rested on

lawful dispensing behavior. *See* Track 3 Verdict Form. The Court must thus presume that the verdict was both preempted by federal law and not cognizable under Ohio nuisance law. *See, e.g.*, *Yates v. United States*, 354 U.S. 298, 312 (1957) ("In these circumstances we think the proper rule to be applied is that which requires a verdict to be set aside in cases where the verdict is supportable on one ground, but not on another, and it is impossible to tell which ground the jury selected.").

C. No Reasonable Juror Could Have Found That Defendants Proximately Caused a Public Nuisance in Lake and Trumbull Counties.

Furthermore, Plaintiffs have introduced no evidence that can establish that Defendants' dispensing conduct caused a present-day nuisance. "[T]he tort of public nuisance only reaches so far," *Cleveland v. JP Morgan Chase Bank, N.A.*, No. 98656, 2013 WL 1183332, at *3 (Ohio Ct. App. Mar. 21, 2013), and "not every failure to comply with [a regulation] amounts to a public nuisance," *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 479 (6th Cir. 2017). The plaintiff must show, in addition, that the violation substantially interfered with public health and safety, *id.*, and that the defendant was a "substantial factor" in causing the alleged harm, Restatement (Second) of Torts § 834 cmt. d (1979); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990).

An actor's conduct is not a substantial factor if the harm would have been sustained even without the misconduct. Restatement (Second) of Torts § 432. Three considerations determine whether a cause is a substantial factor: "(a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it; (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible; [and] (c) lapse of time." *Id.* § 433.

Even more, "to support a verdict and judgment" for public nuisance, a plaintiff must "show[] by the evidence that the injury incurred was the *proximate result* of the maintenance of such nuisance." *Gaines v. Vill. of Wyo.*, 72 N.E.2d 369, 373 (Ohio 1947) (emphasis added). Plaintiffs did not meet these standards with respect to Defendants' dispensing conduct.

No evidence of any particular illegitimate prescriptions. Plaintiffs say that Defendants' failure to identify and refuse to fill illegitimate prescriptions caused their harm. But Plaintiffs introduced no evidence that any such prescription was filled, let alone that one was knowingly filled in violation of 21 C.F.R. § 1306.04(a). Indeed, Plaintiffs presented no evidence that the "red flag" prescriptions identified by their experts were in fact illegitimate. Carmen Catizone admitted as much when he testified that "just because a prescription flags under one of [his] 16 red flags, that does not mean that it was written for an illegitimate medical purpose." Dkt. 4008 at 1208–09 (Oct. 8 trial tr., vol. 5).

That is a critical failure of proof. *See, e.g.*, *State v. Purdue Pharma L.P.*, No. 30-2014-00725287, at 14, 17 (Cal. Super. Ct. Orange Cnty. Nov. 1, 2021) (dismissing analogous nuisance claim where the plaintiffs failed to "distinguish between medically appropriate and medically inappropriate prescriptions" and presented "no evidence that even attempts to quantify how medically inappropriate prescriptions caused or contributed to the opioid crisis"). Without this evidence, Plaintiffs did not establish causation. *See, e.g.*, *Burnworth v. Harper*, 672 N.E.2d 241, 245 (Ohio Ct. App. 1996).

No evidence of any diverted or misused Defendant prescriptions. Even if they had evidence of suspicious prescriptions that (1) were in fact illegitimate, (2) Defendants could have detected and prevented from being filled, and (3) their pharmacies knowingly filled nonetheless, Plaintiffs introduced no evidence at all that any of those prescriptions were in fact diverted or misused in

any way—much less in a way that has resulted in injury to the community at large. Diversion or misuse is the key link in Plaintiffs' alleged causal chain. Without evidence that prescription opioid medications dispensed by *Defendants'* pharmacies were diverted or misused and have resulted in ongoing harm to the community at large, Plaintiffs cannot establish causation. And Plaintiffs must establish proximate cause separately for each Defendant; aggregate proof is not enough. *See Sutowski*, 696 N.E.2d at 190; *Pang*, 559 N.E.2d at 1324. To show harm, Plaintiffs had to show actual diversion or misuse, and they have not shown that a single pill left any of Defendants' pharmacies improperly—that is, with knowledge that it was improper.

No causal chain regardless. Even if Plaintiffs had introduced evidence of illegitimate prescriptions filled at each of Defendants' pharmacies that were later diverted, which they did not, they still cannot show that Defendants proximately caused their alleged injuries.

First, Defendants' dispensing conduct was not nearly material enough to have a "substantial impact" on the opioid crisis. *Schwartz v. Honeywell Int'l, Inc.*, 102 N.E.3d 477, 482 (Ohio 2018); *see Martin v. Cincinnati Gas & Elec. Co.*, 561 F.3d 439, 443 (6th Cir. 2009); Restatement (Second) of Torts § 834 cmt. d. Even among pharmacies, non-defendants accounted for 72% of the market in Lake and Trumbull Counties by MME between 2006 and 2014. WMT-MDL-01541A. According to the former Ohio Board of Pharmacy Agent George Pavlich, those non-defendant independent pharmacies were the "least compliant" with Ohio law and regulations, whereas chain pharmacies like Defendants were "the most compliant." Dkt. 4106 at 4546 (Oct. 28 trial tr., vol. 18). While Pavlich could not recall a single Defendant pharmacy that had its license revoked in the 25 years he worked at the Board, "there were numerous independent ones" that did. *Id.* at 4547; *see also* Dkt. 4111 at 5349–50 (Nov. 2 trial tr., vol. 21) (Edwards testifying that he could not recall a single revocation of a Defendant pharmacy license). And that is not even

accounting for the innumerable other entities and individuals who contributed greatly to any opioid crisis, from federal and state regulators to pharmaceutical manufacturers and criminal traffickers and dealers.

Second, Plaintiffs cannot show proximate causation because they cannot show that Defendants' conduct *directly* caused Plaintiffs' alleged harm. *See City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 502 (6th Cir. 2010) (finding that plaintiff in nuisance suit had failed to prove proximate cause because it had not shown a "direct relation between the injury asserted and the injurious conduct alleged"). Defendants' Lake County and Trumbull County pharmacies played only a tiny—and far-down-the-chain—part in the supply chain. At most, then, they could have had only an *indirect* and *remote* connection to Plaintiffs' alleged injuries. When a public-nuisance defendant plays such a role, it cannot be held liable. *See id.* at 503–04 (collecting cases deciding remoteness as a matter of law); *see also Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1147–48 (Ohio 2002) (adopting directness requirement from *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992)).

A nuisance suit fails this directness requirement when "there is another set of independent actors between the alleged misconduct and the alleged injury." *Ameriquest*, 615 F.3d at 505. "Notably, [the directness] requirement is distinct from foreseeability and applies even if the [d]efendants intentionally caused the alleged course of events." *Id.* at 502.

The most notable independent actors are ones Plaintiffs never sued: prescribers. These medical professionals are the ones who decide which medication, if any, to prescribe to their patients, in what amount, and for how long. If prescribers do not write any opioid prescriptions—whether legitimate or not—then pharmacies have no opioid prescriptions to fill. Those prescribers have independent duties under the CSA to write prescriptions for legitimate medical purposes. *See*

21 C.F.R. § 1306.04(a). Defendants' pharmacists, by contrast, are tasked with refusing to fill prescriptions that they *know* are not written for legitimate medical purposes, a task that never arises if prescribers never write any opioid prescriptions in the first place. In other words, prescribers are the direct causes of any allegedly improper prescriptions that are written and filled.

There are numerous "factors necessary for the harm suffered by the [Counties] to materialize," making Defendants' role too far remote for liability. *Chase*, 2013 WL 1183332, at *4. To name just a few of the factors necessary to have brought about Plaintiffs' harm, *according to Plaintiffs themselves*: The Manufacturer Defendants (Purdue, Cephalon, Janssen, Endo, and Mallinckrodt) allegedly changed the standard of care for pain treatment by misrepresenting the dangers and effectiveness of opioids, thereby leading doctors, with encouragement of the government, to prescribe opioids in unreasonable numbers. *See In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2018 WL 6628898, at *5 (N.D. Ohio Dec. 19, 2018). According to this Court, the Manufacturers may be close enough to a county's claimed injury to survive the directness requirement on the pleadings, because their marketing directly caused "excess opioids" in the counties. *Id.* (stating that "[u]nder this potential chain of causation, the relationship between Plaintiffs' injury and Defendants' alleged conduct . . . is not too remote to support a finding of proximate cause"). But none of this conduct relates to any Defendants' dispensing. Because dispensing by CVS, Walgreens, and Walmart is "completely distinct from th[at] asserted misconduct," it is too remote for liability. *Ameriquest*, 615 F.3d at 504; *see, e.g.*, Dkt. 3253 at 18 (opinion and order granting in part and denying in part Defendants' Motions to Dismiss in *West Boca*, suggesting no remoteness for an injury "at least one step further removed from the [allegedly] injurious conduct.").

The trial testimony of Plaintiffs' causation expert, Dr. Katherine Keyes, merely underscored the remote relationship between Defendants' conduct and Plaintiffs' alleged injury here. She noted that she was tasked with measuring "a complex system" with many "individual vulnerabilities" and "other community level factors." Dkt. 4065 at 3684 (Oct. 22 trial tr., vol. 14). She agreed that major wholesale distributors and drug manufacturers causally contributed to the burden. *Id.* at 3691–92. She also stated that even government entities, including the FDA, DEA, and state medical boards, were "points in [the] access pathway" and played a causal role for their lack of adequate regulation. *Id*. at 3690. Dr. Keyes even admitted that if the opioid manufacturers had "acted more responsibly" and FDA had "done its job," there would not have been an opioid crisis. Dkt. 4090 at 4153 (Oct. 26 trial tr., vol. 16). Plaintiffs' expert Dr. Caleb Alexander, for his part, agreed that he had testified that "the origins of the epidemic are multiple [] including unsubstantiated claims about the safety and effectiveness of opioids, multifaceted campaigns by pharmaceutical companies, and the failure of the FDA and DEA." Dkt. 4064 at 3505 (Oct. 21 trial tr., vol. 13). He also agreed that Manufacturers, FDA, and DEA—not pharmacies—were the "major causes of the opioid epidemic." *Id.* at 3532–33.

Defendants' causation expert, Dr. Kevin Murphy, confirmed this analysis. Dr. Murphy testified that *both* "demand and supply factors" contributed to the rise of opioids in Lake and Trumbull Counties. Dkt. 4118 at 5939 (Nov. 4 trial tr., vol. 23). He testified that Congress created Medicare Part D in 2006, which "made prescription medications more affordable for seniors" and led to a "growth in the use of opioids in particular." *Id.* at 5950. In addition, Dr. Murphy explained that the share of manufacturing jobs in Ohio fell from 35.7% in 1970 to only 15.7% in 2019 and, unlike in many other States, "[n]ot nearly [as] many other jobs came in to replace those." *Id.* at 5970–71. He noted that this dynamic contributed to a drastic decline in the labor force

participation rate in Lake and Trumbull Counties between 20% to 30%. *Id.* at 5973–74. Dr. Murphy explained that "nonparticipation for men is often associated with poor outcomes, health, family, everything." *Id.* at 5974. Thus, he concluded that it was "not surprising[]" that "places where labor force participation decline[d], manufacturing employment decline[d]" were the same "places where opioid mortality also went up." *Id.* at 5975. Finally, Dr. Murphy testified that "changes in the standard in care was another factor that pushed people toward prescription activity" because doctors become "more cognizant of trying to make sure they were handling people's pain." *Id.* at 5955; *see also* Dkt. 4106 at 4700 (Oct. 28 trial tr., vol. 18) (Dr. Wailes testifying that "in the '80s it was very clear that untreated pain was a huge terrible situation[,]" and that "doctors were becoming more aware that so much suffering was out there and they needed treatment of some type"). With all of this happening at the same time, Defendants' dispensing cannot be the proximate cause of Plaintiffs' asserted injuries. *See, e.g.*, *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006).

Third, Plaintiffs' chain of causation is further attenuated by several criminal causes of their alleged injuries. Some of these criminal acts actually *intervened* in the alleged causal chain between Defendants' conduct and Plaintiffs' alleged harms. *See Cascone v. Herb Kay Co.*, 451 N.E.2d 815, 819–20 (Ohio 1983); *see also* Dkt. 497-1 at 28–29. For example, Dr. Keyes agreed that "medicine cabinet diversion" and theft all helped cause the overdose burden in Plaintiffs' Counties. *See, e.g.*, Dkt. 4065 at 4688–89 (Oct. 22 trial tr., vol. 14); Dkt. 4090 at 4090 (Oct. 26 trial tr., vol. 16) (Dr. Keyes testifying there is "an extraordinary amount of unused opioids"); Dkt. 4064 at 3522 (Oct. 21 trial tr., vol. 13) (Dr. Alexander agreeing that "70 percent of people who report nonmedical use of prescription opioids state their most recently used drug came from a friend or family member"); Dkt 4093 at 4393–94 (Oct. 27 trial tr., vol. 17) (Lake County addiction

official Kim Fraser agreeing that "excess pills in medicine cabinets [of] friends, family, [and] visitors" contributed to the crisis). Those criminal acts severed any causal chain between Defendants' conduct and Plaintiffs' alleged harm.

Additionally, Plaintiffs' expert Dr. Keyes testified that illicit opioids, including heroin, fentanyl, and counterfeit pills (largely trafficked into the United States from China and Mexico) independently contributed to the burden in Lake and Trumbull Counties. *See, e.g.*, Dkt. 4065 at 3684–88 (Oct. 22 trial tr., vol. 14). Dr. Murphy reached an even stronger conclusion. When addressing the post-2010 period, Dr. Murphy testified: "It's clearly not prescription opioids that have led to the explosion in deaths in this later period. It's not people overdosing on prescription opioids. It's people overdosing on illegal drugs . . . particularly fentanyl. Fentanyl is a big part of the growth in mortality story in this later period." Dkt. 4118 at 5983 (Nov. 4 trial tr., vol. 23). In fact, there has been "more than a 50 percent decline in prescription opioid shipments on a per capita basis to Ohio since 2010–11" even as "deaths from heroin, and particularly fentanyl [went] way up." *Id.* at 5986; *see also* Dkt. 4106 at 4739–40 (Dr. Wailes testifying that prescription opioid use has "fallen off 43 percent in the last 9 or 10 years").

This problem cannot be explained away by Plaintiffs' claim that prescription opioids served as a gateway to illicit drugs. Dr. Murphy showed through data analysis that it was "not the same people that were getting [opioid] prescriptions who were later dying of heroin and fentanyl." Dkt. 4118 at 5990 (Nov. 4 trial tr., vol. 23). Moreover, the so-called gateway thesis "ignore[s] [] other pathway[s][,]" including the possibility that an individual may "initiate on illegal opioids, like heroin or fentanyl[,]" which is becoming "an empirical reality [] over time, more and more." *Id.* at 5942–43. And perhaps most importantly, heroin use is the result of illicit activity by

intervening criminal actors—both dealers and users—that by definition is not the direct result of the conduct of Defendants in filling prescriptions, written by doctors, for lawful medication.

Fourth, the prescribing behavior of medical professionals was yet another independent cause of Plaintiffs' alleged harm. Plaintiffs' dispensing theory rests on an alleged causal chain that involves the conduct of prescribing doctors and other medical professionals, who—if improper prescriptions were in fact presented to Defendants' pharmacies—necessarily violated the CSA before Defendants allegedly did. *See* 21 C.F.R. § 1306.04(a) (placing the "responsibility for the proper prescribing and dispensing of controlled substances" on "the prescribing practitioner"). Indeed, Dr. Keyes herself agreed that the opioid crisis would not have occurred if prescribing opioids had not become the standard medical practice for managing pain in patients. Dkt. 4065 at 3693 (Oct. 22 trial tr., vol. 14).

Defendants and their pharmacists appropriately relied on prescribing medical professionals to evaluate manufacturers' marketing and set the standard of care. Without knowledge of illicit behavior—and there has been no evidence of any such knowledge in this case—Defendants' pharmacists "reasonably assume[d] that the physician [would] exercise his informed judgment in the patient's best interests." *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878–79 (Ohio 1991); *see, e.g.*, *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 596 (S.D. Ohio 2003) (dismissing claims against opioid manufacturers on this basis).

The harm supposedly caused by each Defendant's dispensing, as opposed to any other party or nonparty and its separate conduct, is diffuse and difficult to quantify. That is even further confirmation that causation, if any, is too remote and cannot satisfy proximate causation. *Chase*, 2013 WL 1183332, at *5 (noting that "difficult to calculate" damages are sign of remote cause). "[T]he less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's

damages attributable to the violation, as distinct from other, independent, factors." *Holmes*, 503 U.S. at 269. There is no feasible way to measure how much any given Defendant's dispensing contributed to the "increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's community." Dkt. 3327 ¶ 626 (Track 3 Supplemental and Amended Allegations). All these alleged harms "could have been caused by many other factors unconnected to [Defendants'] conduct," *Ameriquest*, 615 F.3d at 504, including the conduct that this Court already held was directly connected to those harms, *see* 2018 WL 6628898, at *5.[1] Defendants thus cannot be liable as a matter of law for Plaintiffs' dispensing claims.

II. PLAINTIFFS' NUISANCE CLAIM FAILS AS A MATTER OF LAW.

Defendants have also offered several reasons why Plaintiffs' claims are legally deficient, regardless of the evidence they produced at trial—which, by definition, means Plaintiffs cannot provide a legally sufficient evidentiary basis for their claims. Although the Court has rejected each of these arguments, *see* Dkt. 1032 (Order Denying Track 1B Motions to Dismiss); Dkt. 3403 (Order Denying Pharmacy Defendants' Track 3 Motion to Dismiss), Defendants restate them here to preserve them for appeal.

[1] Plaintiffs are wrong if they claim that *Beretta* somehow helps them overcome these problems. For one thing, both the Ohio General Assembly (through the Ohio Products Liability Act, Ohio Rev. Code Ann. § 2305.10) and the U.S. Congress (through the Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, 119 Stat. 2095 (2005) (codified at 15 U.S.C. §§ 7901–03)) abandoned this case as an undue expansion of nuisance doctrine. For another thing, "[t]he involvement of so many independent actors also reveals why [Plaintiffs'] reliance on *Beretta* is misplaced." *Ameriquest*, 615 F.3d at 505. "*Beretta* has key differences"—chief among them that "through the direct action of the gun manufacturers" sued in *Beretta, and no one else*, "a black market for the illegal sale and distribution of firearms" allegedly existed. *Chase*, 2013 WL 1183332, at *6. Defendants' pharmacies, on the other hand, did not by themselves "create the cocktail of factors that led to" the opioid crisis. *Id.*; *see Ameriquest*, 615 F.3d at 505 (limiting *Beretta*). Thus, Plaintiffs have not proved and cannot prove that any damages they have suffered were proximately caused by any Defendant's dispensing conduct.

A. Ohio Statutory Law Precludes Plaintiffs' Common-Law Nuisance Suit.

Ohio law does not permit a common-law public-nuisance claim based on a pharmacy's alleged failure to detect and prevent the diversion of drugs of abuse.

1. The Ohio Product Liability Act expressly bars Plaintiffs' nuisance claim. This bar includes "public nuisance claim[s] . . . in which it is alleged that the . . . supply, . . . distribution, . . . or sale of a product unreasonably interferes with a right common to the general public." Ohio Rev. Code Ann. § 2307.71(A)(13). Plaintiffs' suit here is just such a barred claim. This Court erred by earlier concluding that Plaintiffs are asserting a non-abrogated claim for equitable relief: among other reasons, the "abatement" Plaintiffs seek is the payment of billions of dollars, some of it for backward-looking damages. *See* Dkt. 491-1 at 35–39.

2. Ohio also comprehensively regulates controlled substances, including by providing the specific path (with specific remedies) to pursue for public-nuisance suits related to dispensing controlled substances. The relevant statute, Ohio Rev. Code Ann. § 4729.35, permits lawsuits against pharmacies based on the allegedly unlawful manner of selling controlled substances—but exclusively in the manner specified by the statute, including, most notably here, only for an injunction. Plaintiffs purport to ground their nuisance claim in common law rather than this statute. But Ohio law does not permit a plaintiff to bring a common-law claim where, as here, the Ohio legislature has comprehensively regulated the field and provided specific remedies that conflict with the common-law cause of action. *See Thompson v. Ford*, 128 N.E.2d 111, 115–16 (Ohio 1955); *Bolles v. Toledo Tr. Co.*, 58 N.E.2d 381, 392 (Ohio 1944); *see also* Dkt. 3340-1 at 13–19. Plaintiffs' claim is thus precluded.

B. Ohio Common Law Precludes Plaintiffs' Public-Nuisance Suit.

Even as a matter of common law, Plaintiffs' theory is not viable. Defendants owe no duty to Plaintiffs for their dispensing conduct under Ohio nuisance law.

1. *Plaintiffs seek an unprecedented expansion of nuisance contrary to public policy*. Plaintiffs' product-based nuisance theory must be rejected on public-policy grounds and as an illegitimate expansion of Ohio common law. *See* Dkt. 491-1 at 35–39 (Distributor Defendants' Track 1B Motion to Dismiss).

It cannot be that any product that poses any health or safety risks to the user or public can create billions of dollars of nuisance liability to compensate for any harm that might have resulted from an end-user's misuse of the product. *See Tioga*, 984 F.2d at 921 (stating that if law recognized products-based nuisance claims, "[n]uisance . . . would become a monster that would devour in one gulp the entire law of tort"); *State ex rel. Hunter v. Johnson & Johnson*, 2021 OK 54, 2021 WL 5191372, at *12 (Okla. 2021) (Kuehn, J., specially concurring) ("If the public nuisance law can be broadly interpreted as is suggested by [Plaintiffs], I believe the law will become the newest fictional shape-shifting monster."); *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 521 (Mich. Ct. App. 1992) (concluding that allowing product-based nuisance claims "would significantly expand, with unpredictable consequences, the remedies already available to persons injured by products").

The Oklahoma Supreme Court recently reached this exact conclusion in a related case, ruling that opioid manufacturers cannot be found liable for the public health effects of opioid abuse based on a public nuisance theory. The State's court of last resort reversed a $465 million bench trial verdict against Johnson & Johnson, finding that the State's public nuisance theory of liability was "fundamentally ill-suited to resolve" claims centering on Johnson & Johnson's manufacture and sale of opioids. *Johnson & Johnson*, 2021 OK 54, ¶ 23. The Oklahoma Supreme Court made it clear that nuisance is not the appropriate vehicle through which to prosecute claims that are, at heart, products-liability claims. The court highlighted that there is a "clear national trend" against

"products-based public nuisance claims" with courts consistently honoring the "common law criminal and property-based limitations" of public nuisance. *Id.* ¶¶ 35, 37.

Indeed, extending public nuisance to the opioid crisis would "allow consumers to convert almost every products liability action into a public nuisance claim." *Id.* ¶ 34 (quotation marks and alteration omitted). The court reasoned that allowing public nuisance to address such "policy problems" rather than "discrete, localized problems" would leave Oklahoma's nuisance statute "impermissibly vague" and allow "courts to manage public policy matters that should be dealt with by the legislative and executive branches." *Id.* ¶ 39.[2]

Absent Ohio cases expanding the common law in this way, this Court has no authority to do so. *See Berrington v. Wal-Mart Stores, Inc.*, 696 F.3d 604, 610 (6th Cir. 2012). "[W]hen given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability," federal courts sitting in diversity "should choose the narrower and more reasonable path." *Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004). They should be "extremely cautious about adopting 'substantive innovation' in state law" and should not endorse "fundamental policy innovation[s]" when the State has not already done so. *Id.* at 578. Charting this narrower path here means Plaintiffs' novel theory must fail.

2. *Plaintiffs cannot show the violation of a public right.* "To recover damages under a claim of public nuisance, the plaintiff must establish," among other things, "an interference with a

[2] This recent decision from Oklahoma builds upon on other decisions rejecting public nuisance claims in opioid litigation, including courts in California, Connecticut, Delaware, Illinois, North Dakota, and South Dakota. *See*, *e.g.*, *State v. Purdue Pharma L.P.*, No. 30-2014-00725287 (Cal. Super. Ct. Orange Cnty. Nov. 1, 2021); *State ex rel. Ravnsborg v. Purdue Pharma, L.P.*, No. 32CIV18-000065 (S.D. Cir. Ct. 6th Jud. Dist. Mar 29, 2021); *State v. Johnson & Johnson*, No. 19 CH 10481 (Ill. Cir. Ct. Cook Cnty. Jan. 8, 2021); *State ex rel. Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-CV-01300, 2019 WL 2245743 (N.D. Dist. Ct. May 10, 2019) (judgment entered May 24, 2019); *State ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382 (Del. Super. Ct. Feb. 4, 2019); *City of New Haven v. Purdue Pharma, L.P.*, No. X07HHDCV176086134S, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019).

public right." *Kramer v. Angel's Path, L.L.C*, 882 N.E.2d 46, 52 (Ohio Ct. App. 2007). But there is no common law "public right to be free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a manner that may create a risk of harm to another." *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004). Put differently, the right not to be negligently injured by a product or by another person's misuse of a product is a *private* right, not a public right. *See Kramer*, 882 N.E.2d at 52 ("A public nuisance will not arise because a large number of people are affected; rather, it arises only when a public right has been affected."); Restatement (Second) of Torts § 821B cmt. g (same, comparing to "the individual right that everyone has not to be assaulted . . . or negligently injured").

The Oklahoma Supreme Court in *Johnson & Johnson* observed that "a public right is more than an aggregate of private rights by a large number of injured people," and concluded that the "damages the State seeks are not for a communal injury but are instead more in line with a private tort action for individual injuries sustained from use of a lawful product and in providing medical treatment or preventive treatment to certain, though numerous, individuals." *Johnson & Johnson*, 2021 OK 54, ¶ 24. So too here. Plaintiffs accordingly cannot base their public-nuisance claim on the private misuse of opioid medications and are thus unable to prove the invasion of a public right. *See* Dkt. 491-1 at 39–42; Dkt. 497-1 at 27; Dkt. 3340-1 at 37.

3. *Plaintiffs cannot show that Defendants' highly regulated dispensing conduct constitutes a nuisance*. Plaintiffs cannot base their nuisance claim on Defendants' highly regulated dispensing conduct. *See* Dkt. 491-1 at 42–43; Dkt. 497-1 at 26–27; Dkt. 3340-1 at 37.

An absolute nuisance ordinarily involves an inherently dangerous activity "that cannot be maintained without injury to property, no matter what precautions are taken." *Kramer*, 882 N.E.2d

at 52. But Plaintiffs' entire theory of the case at trial is that opioids *can* be dispensed safely, and that Defendants can be faulted for not doing so. And irrespective of Plaintiffs' view, the fact is that dispensing prescription opioid medications remains authorized, yet extensively regulated, by state and federal law for critical public policy reasons. No "actionable" nuisance tort lies where, as here, "a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct exist." *Brown*, 622 N.E.2d at 1158–60; 58 Am. Jur. 2d Nuisances § 8 (Nov. 21 update) (stating that public nuisances always arise out of unlawful acts, and that which is lawful, or is authorized by a valid statute, or which the public convenience imperatively demands, cannot be a public nuisance).

4. *Defendants have no control over the opioid medications at the time of the alleged nuisance.* This Court cannot expand Ohio's common law by eliminating the traditional "control" element of a nuisance claim—an element Plaintiffs did not allege and cannot prove.

Ohio public nuisance law has long contained a control element. *See, e.g.*, *Kramer*, 882 N.E.2d at 56 (no nuisance "absent any evidence of such a right of possession or control" because the defendant then "has no ability to create or prevent [the] nuisance"); *see also Taylor v. City of Cincinnati*, 55 N.E.2d 724, 725 (Ohio 1944) (syllabus ¶ 2, defining the traditional elements of "[a]bsolute nuisance" to include the defendant's "control or direction" of the supposedly nuisance-causing land or instrumentality). The control element makes sense because "the principal remedy for the harm caused by the nuisance is abatement," and the defendant cannot abate a nuisance if it no longer has control over what created it. *State v. Lead Indus. Ass'n*, 951 A.2d 428, 449 (R.I. 2008). Other plaintiffs' failures to satisfy this element have led to dismissals of many similar lawsuits. *See, e.g.*, *City of Manchester v. Nat'l Gypsum Co.*, 637 F. Supp. 646, 656 (D.R.I. 1986) (asbestos manufacturers were not liable for nuisance after they relinquished control over the

asbestos); *Lead Indus*., 951 A.2d at 449 (paint manufacturers were not liable for nuisance when they lacked "control over the [paint] . . . *at the time the damage occur[ed]*"). This even includes cases involving opioids: A "defendant is not liable for public nuisance unless it exercises control over the instrumentality that caused the nuisance *at the time of the nuisance*," and thus opioids plaintiffs cannot show "control by [d]efendants over the instrumentality [opioids] at the time of the [alleged] nuisance"—i.e., when third parties diverted the opioids and used them illegally. *State ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382, at *13 (Del. Super. Ct. Feb. 4, 2019) (emphasis added); *Johnson & Johnson*, 2021 OK 54, ¶ 27 (dismissing public nuisance claim because Johnson & Johnson "did not control the instrumentality alleged to constitute the nuisance at the time it occurred").

This Court, sitting in diversity, may not abolish or expand the control element. *See Combs*, 354 F.3d at 577. It thus may not hold pharmacies liable for the supposed nuisance created after the opioids left their control. The evidence submitted at trial shows that any effects of the nuisance did not occur while opioids were behind the counter in a pharmacy. Instead, they occurred only *after* the drugs were dispensed—that is, *after* they left Defendants' control.

5. *The CSA and its Ohio analog are not predicate "safety statutes."* Plaintiffs also cannot prove the violation of a "safety statute," as required to prove liability under the "unlawful" prong of absolute nuisance. *See* 1 Ohio Jury Instructions CV 621.01; Dkt. 3449 at 81 n.49 (Defendants' Track 1B proposed jury instructions). A statute is a "safety statute" only if it sets forth a "*specific* legal requirement for the protection of others." *Taylor*, 55 N.E.2d at 728 (emphasis added). A statute sets forth a "specific" requirement where "a jury may determine whether there has been a violation thereof by finding a single issue of fact." *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 201 (Ohio 1998). In that sense a claim for absolute public nuisance based on a violation of a safety

statute resembles a private plaintiff's claim for negligence *per se*. *Uland v. S.E. Johnson Cos.*, No. WM-97-005, 1998 WL 123086, at *5 (Ohio Ct. App. Mar. 13, 1998) (liability for an absolute nuisance based on the violation of a safety statute is equivalent to liability for negligence *per se*).

Plaintiffs' absolute nuisance claim rests on regulatory violations of the CSA, but those provisions and their Ohio analogs are *not* safety statutes because they contain no private right of action. *See Smrtka v. Boote*, 88 N.E.3d 465, 474 (Ohio Ct. App. 2017) ("A negligence *per se* claim is not appropriate when 'the legislative enactment in question does not define a civil liability but instead only "makes provision to secure the safety or welfare of the public."') (quoting *Moreland v. Oak Creek OB/GYN, Inc.*, 970 N.E.2d 455, 462 (Ohio Ct. App. 2005)); *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290–91 (D. Colo. 2016). And the violation of *regulations* interpreting the CSA is insufficient for *per se* liability. *Chambers*, 697 N.E.2d at 202–03 (noting that to "bestow upon administrative agencies the ability to propose and adopt rules that alter the proof requirements between litigants . . . would be tantamount to an unconstitutional delegation of legislative authority, since administrative agencies cannot dictate public policy"). Finally, the jury would need to make more than a single finding of fact to determine whether the alleged dispensing duties at issue here were violated. *See id.* at 201; *Becker v. Shaull*, 584 N.E.2d 684, 685–87 (Ohio 1992) (no negligence *per se* when the jury would have to make multiple findings of fact); *cf.* Dkt. 2483 at 29 (suspicious order duties would require multiple findings of fact). For all of these reasons, no reasonable jury could find that any of the Defendants acted "unlawfully" by violating a "safety statute" through their dispensing conduct.

C. Defendants Owe No Duty to Plaintiffs for Their Dispensing Conduct Under the CSA or Its Ohio Analog.

Under the CSA, Defendants owe no corporate-level duty to Plaintiffs for their dispensing conduct. Even if such a regulatory duty existed, Defendants would not owe it to Plaintiffs. In any event, the CSA preempts Plaintiffs' claims and contains no private right of action.

1. *Defendants did not owe the corporate-level dispensing duties on which Plaintiffs base their nuisance claim*. Plaintiffs' public-nuisance claim fails as to dispensing because they cannot point to any provision of the CSA or its related regulations that Defendants violated. *See* Dkt. 3340-1 at 20–26 (Pharmacy Defendants' Track 3 Motion to Dismiss). There is no evidence that Defendants failed to comply with the physical-security, recordkeeping, and licensing requirements in the CSA. Most critically, Plaintiffs did not produce a shred of evidence to suggest that Defendants employed unlicensed pharmacists. *See* 21 C.F.R. § 1306.06. Nor did they show that Defendants' pharmacists (let alone those in Plaintiffs' Counties) knowingly filled even a single prescription that was not prescribed for a legitimate medical purpose in the usual course of professional treatment. *Id.* § 1306.04(a).

That should be the end of the case. Any CSA-related duties must derive from the CSA's text or its regulations, not from guidance documents, DEA administrative rulings regarding licensing revocations, or anything else. Plaintiffs nonetheless argue that Defendants violated the CSA, at the corporate level, by not alerting their pharmacists to certain "red flags" and requiring them to resolve such flags through documentation and by allowing them to fill illegitimate prescriptions. But the obligation to evaluate a prescription and guard against dispensing-based diversion resides not at the corporate level but with the individual pharmacist presented with a prescription. The regulation could not be clearer: "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding

responsibility rests with *the pharmacist who fills the prescription*." *Id.* § 1306.04(a) (emphasis added); *see also* Ohio Admin. Code § 4729-5-21(A) (same); Ohio Admin. Code § 4729-5-30(A) (same). The regulatory text assigns primary responsibility for ensuring the proper prescribing and dispensing of controlled substances to the doctor or other prescriber and a "corresponding" responsibility to the "pharmacist" who fills the prescription.

Resisting this plain text, Plaintiffs cite 21 C.F.R. § 1301.71(a), which requires all registrants (including pharmacies) to provide effective controls to guard against the theft and diversion of controlled substances. But for pharmacies, this regulation imposes only requirements for in-store physical security controls and has never been understood to require a "system" for monitoring prescriptions and disclosing "suspicious orders of controlled substances," *id.* § 1301.74(a)–(b) (applying this "system" requirement only to distributors of controlled substances); *see also, e.g.*, *ChipRX, L.L.C., d/b/a City Center Pharmacy*; *Decision and Order*, 82 Fed. Reg. 51,433-02, 51,434 (Nov. 6, 2017) (finding that the pharmacy was alleged to have failed to maintain effective controls against diversion and theft because the pharmacist-in-charge was routinely stealing controlled substances to fuel his own addiction and deleting surveillance video footage of his unlawful removal of controlled substances from the pharmacy premises).

Like Ohio law, DEA regulations define "pharmacist" as a state-licensed professional *individual*, not a pharmacy corporation. 21 C.F.R. § 1300.01; Ohio Admin. Code § 4729:1-1-01(M). The regulation's description of a pharmacist's responsibility as "corresponding" to the responsibility of the "prescribing practitioner" reinforces that the obligation rests with the pharmacist, not the corporate owner. These responsibilities are *professional* in nature—demanding the exercise of specialized judgment by a professional who has earned the required degree and is trained and licensed in a regulated discipline.

Altogether, Plaintiffs' novel theory that Defendants had a corporate-level duty to enact specific systems, policies, or procedures to prevent improper dispensing cannot be reconciled with the sources of law on which Plaintiffs rely. *See* Dkt. 3499 at 7 (stating that "there is no absolute requirement, for example, that a pharmacy must conduct a computerized red-flag analysis of each prescription before filling it"). And even if such a regulatory duty existed, it would not be owed to Plaintiffs.

2. *Penalizing Defendants for dispensing conduct that does not violate the CSA would stand as an obstacle to Congress's objectives and is thus preempted.* Any theory of the case that seeks to penalize Defendants for dispensing conduct that *does not violate* the CSA would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and thus be preempted by federal law. *Arizona*, 567 U.S. at 399–400. Congress enacted the CSA to "control the supply and demand of controlled substances," *Gonzales v. Raich*, 545 U.S. 1, 19 (2005). In doing so, Congress sought to balance two related concerns. Many regulated drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). But "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." *Id.* § 801(2).

The Act's regulatory scheme is designed to strike a balance between "foster[ing] the beneficial use of those medications" while also "prevent[ing] their misuse." *Raich*, 545 U.S. at 24. Congress vested DEA with the authority to promulgate regulations (through notice-and-comment rulemaking) and to enforce the statute with both these considerations in mind. Holding Defendants liable for dispensing conduct under Ohio nuisance law that Congress considered and

allowed under the CSA would thus "skew[]" the "delicate balance of statutory objectives" set by federal law. *Buckman Co.*, 531 U.S. at 348.

Plaintiffs' common law tort theory is also preempted because it would also interfere with the discretion Congress gave DEA. *See Raich*, 545 U.S. at 19 (CSA covers and preempts the field of controlled substances). The CSA grants DEA the authority to determine whether it is inconsistent with the public interest to allow an entity to distribute or dispense controlled substances, which includes DEA's assessment of whether a distributor has "effective controls" against diversion. *See* 21 U.S.C. § 823(b). Once DEA approves a registration, the pharmacy is "*authorized* to . . . distribute[] or dispense controlled substances." *Id.* § 822(b) (emphasis added). Plaintiffs, however, seek to hold Defendants liable for exactly what DEA has "authorized" and thereby leverage Ohio nuisance law to second-guess the judgment of the expert federal agency Congress tasked with making the relevant judgment. Plaintiffs themselves have even acknowledged that any claims based on conduct that complied with the CSA would be preempted. *See* Dkt. 3464 at 29 ("The point is that the Pharmacy Defendants **did not** comply with the CSA when distributing their opioid products. There is no preemption issue. . . ." (emphasis in original)). But it is up to DEA, not a jury, to determine whether registration of a pharmacist is in the public interest.

Indeed, DEA is permitted "to maintain and not revoke the registration of a registrant despite violations of the CSA," so long as the registrant substantially complies with the law. *See* Dkt. 4075 (Plaintiffs' proposed jury instruction); 21 C.F.R. § 1301.71(b). DEA is even granted broad discretion to waive the registration requirement altogether, so long as it is "consistent with the public health and safety." 21 U.S.C. § 822(d). Time and time again, the CSA grants DEA discretion over what conduct suffices and does not suffice to warrant registration and, along with

it, authorization to dispense controlled substances. Plaintiffs' lawsuit completely removes DEA from this equation, asking a lay jury to decide for themselves what is authorized and what is not in the first instance. Such an approach is inconsistent with the text and design of the CSA.

Plaintiffs' theory also offends due process. The imposition of common law tort liability is an exercise of state power that must comply with the "fair notice" requirements of due process. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996). Plaintiffs cannot use a tort lawsuit either to retroactively change the regulations under which Defendants were "authorized" to operate or to retroactively overturn its record of compliance with those regulations. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992) (noting that a "[state] regulation can be as effectively exerted through an award of damages as through some form of [preventative] relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy"). Plaintiffs' attempt to retroactively rewrite the law and re-regulate Defendants usurps the role of the regulator, denies Defendants the fair notice to which they are entitled, and encourages standardless, arbitrary, and contradictory enforcement of comprehensive regulations by private litigants.

3. *The CSA does not give Plaintiffs a private right of action to sue Defendants even for dispensing conduct that does violate the Act.* DEA's enforcement authority is exclusive, precluding private suits. The agency's regulations elaborating on "effective controls against diversion" set the criteria for *DEA* to use to license dispensers of controlled substances; they do not impose duties that *municipalities* can enforce in a common-law suit. *See* Dkt. 491-1 at 48–56; Dkt. 497-1 at 18–21; Dkt. 3340-1 at 36. Courts recognize that "according to its plain terms, '[t]he [CSA] is a statute enforceable only by the Attorney General and, by delegation, the Department of

Justice.'" *Smith*, 164 F. Supp. 3d at 1290 (quoting *Schneller ex rel. Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 293 (3d Cir. 2010) (per curiam)).

As a result, federal courts—including in opioid cases—"have uniformly held that the [federal] CSA does not create a private right of action." *E.g.*, *Smith*, 164 F. Supp. 3d at 1290; Memorandum Opinion and Order at 14–15, *West Virginia v. McKesson Corp.*, No. 17-cv-03555 (S.D. W. Va. Feb. 15, 2018); *McKesson Corp. v. Hembree*, No. 17-cv-323, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018). Plaintiffs' efforts to enforce statutory and regulatory duties through common-law nuisance "would, in effect, be permitting a private cause of action under" the statute or regulation and should not be allowed. *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994). Thus, no matter if Plaintiffs are right about what corporate-level duties Defendants had under the CSA, Plaintiffs have no legal right to enforce them.

4. *Plaintiffs' claims are barred by the primary jurisdiction doctrine.* For reasons similar to why Plaintiffs' claims are preempted by the CSA, those claims are also barred by the primary jurisdiction doctrine. Under that doctrine, federal courts refrain from adjudicating claims that require resolution of issues within the "special competence" of a federal agency. *Charvat v. EchoStar Satellite, LLC*, 630 F.3d 459, 466 (6th Cir. 2010). A court should leave an issue to an agency "for a variety of reasons: (1) to advance regulatory uniformity; (2) to answer a 'question . . . within the agency's discretion'; and (3) to benefit from 'technical or policy considerations within the agency's . . . expertise.'" *Id.* (citations omitted). These reasons require this Court to leave the question of whether Defendants have complied with the CSA to DEA. After all, Congress entrusted DEA alone with broad discretion to enforce the CSA uniformly by balancing the regulatory scheme's goals of "foster[ing] the beneficial use of . . . medications," while "prevent[ing] their misuse." *Raich*, 545 U.S. at 24.

D. Plaintiffs' Nuisance Claim Fails for Additional Legal Reasons.

1. *Standing*. Plaintiffs lack standing—both of the prudential (public-nuisance) and Article III variety. Public-nuisance claims fail on remoteness grounds either if there is no "direct relationship between [Plaintiffs'] harm and Defendants' conduct" (causation, *supra* Section I.C), or if the harm "is wholly derivative of the harm suffered by a third party" ("prudential standing"). *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 621 F. Supp. 2d 513, 532 (N.D. Ohio 2009), *aff'd*, 615 F.3d 496. Plaintiffs lack prudential standing because their alleged injuries are wholly derivative of the harm suffered by third parties: the Counties' residents. *See, e.g.*, *id.*; *Laborers Loc. 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 235 (2d Cir. 1999); *see also* Dkt. 497-1 at 23; Dkt. 491-1 at 58–62. And Plaintiffs lack Article III standing to sue for indirect injuries incurred in the first instance by others. *See Coyne v. Am. Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999); *see also* Dkt. 497-1 at 11–14, Dkt. 3340-1 at 36.

Moreover, as the Supreme Court recently underscored in *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021), Article III does not permit Plaintiffs to regulate mere regulatory non-compliance. "Federal courts do not possess a roving commission to publicly opine on every legal question," nor do they "exercise general legal oversight . . . of private entities." *Id.* at 2203. Like other plaintiffs, the Counties "are not charged with pursuing the public interest in enforcing a defendant's general compliance with regulatory law." *Id.* at 2207. Congress instead tasked DEA with that responsibility. It is thus insufficient for Plaintiffs to rely on regulatory noncompliance, or an allegedly increased risk of harm stemming from regulatory noncompliance, as a basis for Article III standing. *Id.* at 2211.

2. *Economic Loss Doctrine*. The economic loss doctrine bars Plaintiffs' claim. *See* Dkt. 491-1 at 56–57, Dkt. 3340-1 at 36. "The doctrine bars tort plaintiffs from recovering purely economic loss that does not arise from tangible physical injury to persons or property." *Deutsche*

Bank, 863 F.3d at 477 (cleaned up); *see id.* at 477–78 (collecting cases). A "claim of absolute nuisance [thus] requires that the plaintiff sustain injury to property"—its own person or property—and Plaintiffs have not shown (or even alleged) that here. *RWP, Inc. v. Fabrizi Trucking & Paving Co.*, No. 87382, 2006 WL 2777159, at *4 (Ohio Ct. App. Sept. 28, 2006); *see, e.g.*, *Ameriquest*, 621 F. Supp. 2d at 522–26.

Contrary to this Court's pretrial conclusion, there is no persuasive indication in Ohio law that the economic loss rule does not apply, or applies differently, to claims of absolute public nuisance like this one. The decision in *Eysoldt* v. *ProScan Imaging*, 957 N.E.2d 780 (Ohio Ct. App. 2011), was not a nuisance case; it considered claims for conversion and invasion of privacy when the defendant website hosting company had a direct relationship with the plaintiffs, who were customers. No such relationship between Plaintiffs and Defendants exists here. Any liability would arise from an underlying contractual relationship between Defendants and their customers, not from a direct duty or special relationship between Plaintiffs and Defendants. *See also* Restatement (Third) of Torts: Liab. for Econ. Harm § 8 cmt. g (2020) (generally no liability in public nuisance for economic harm caused by products).

3. *Statewide Concern Doctrine*. Plaintiffs' claims are also barred and preempted by the statewide concern doctrine. *See* Dkt. 491-1 at 57–58, Dkt. 3340-1 at 36. Simply put, "[i]t is a fundamental principle of Ohio law that, pursuant to the 'statewide concern' doctrine, a municipality may not, in the regulation of local matters, infringe on matters of general and statewide concern." *Am. Fin. Servs. Ass'n v. City of Cleveland*, 858 N.E.2d 776, 781 (Ohio 2006). The municipality Plaintiffs here seek to regulate and infringe on a matter of the most general concern. *See Chase*, 2013 WL 1183332, at *6 (action for "money judgment stemming from common-law suits may constitute regulation"); *Ameriquest*, 621 F. Supp. 2d at 518 ("Without

question, common law actions for damages represent an important manner of regulating conduct."). Ohio courts would not allow it, and neither may this Court.

4. *Municipal cost recovery rule*. This rule, also known as the free public services doctrine, further bars Plaintiffs' claims. Under this doctrine, "public expenditures made in the performance of governmental functions"—like those allegedly spent by Plaintiffs here—"are not recoverable in tort." *Beretta*, 821 N.E.2d at 1144. Decisions over how and whether to allocate certain costs, including the costs to address the opioid crisis, "necessarily implicate[] fiscal policy, a matter best left to 'the legislature and its public deliberative processes, rather than the court'" (especially a federal court). *Walker Cnty. v. Tri-State Crematory*, 643 S.E.2d 324, 327 (Ga. Ct. App. 2007). This doctrine squarely applies, and no exceptions allow the suit to proceed.

5. *Statute of Limitations*. Plaintiffs' public-nuisance claim is barred by the two-year Ohio Product Liability Act ("OPLA") statute of limitations, Ohio Rev. Code Ann. § 2305.10, but even if OPLA does not apply, it is barred under the more general four-year statute of limitations for tort suits "[f]or an injury to the rights of the plaintiff not arising on contract," *id.* § 2305.09. *See, e.g.*, *Ashtabula River Corp. Grp. II v. Conrail, Inc.*, 549 F. Supp. 2d 981, 984 (N.D. Ohio 2008); *see also* Dkt. 1874; Dkt. 3340-1 at 36–37.

Under Ohio law, nuisances are either permanent or continuing. *Kramer*, 882 N.E.2d at 52; *see also Sexton v. Mason*, 883 N.E.2d 1013, 1021 (Ohio 2008); *Ashtabula River Corp.*, 549 F. Supp. 2d at 984; *Brown v. Whirlpool Corp.*, 996 F. Supp. 2d 623, 642–43 (N.D. Ohio 2014). "A continuing nuisance arises when the wrongdoer's tortious conduct is ongoing, perpetually generating new violations. Conversely, a permanent nuisance occurs when the wrongdoer's tortious act has been completed, but the plaintiff *continues to experience injury in the absence of any further activity by the defendant*." *Kramer*, 882 N.E.2d at 52 (emphasis added) (citation

omitted); *see also Sexton*, 883 N.E.2d at 1018 (explaining that "a permanent trespass occurs when the defendant's tortious act has been fully accomplished . . . [t]hat is, a trespass under Ohio law is a continuing trespass only if the trespass itself, and not the ongoing injury or harm caused by a past, completed misdeed, is continuing").

Throughout the trial, Plaintiffs acknowledged that Defendants' alleged misconduct occurred years ago and is not continuing today. Plaintiffs' claims are based on indirect injuries from past conduct "in the absence of any further activity by the defendant," not on a continuing nuisance. As Plaintiffs' counsel stated in their opening:

> The problems folks face today is not something that happened because of bad policies yesterday. The bad policies go back into the 2000s; 1999 to 2010, '11, '12, '13, '14. And the problem with this is you get a lot of people addicted to some of these . . . prescription opiates, and then all of a sudden, you cut off the prescriptions, and that availability is not on the street, and they've got an opiate addiction. So at that point in time, they've got to seek out the illegal opiates.

Dkt. 3991 at 77 (Oct. 4 trial tr., vol. 1). The "illegal opiates" are chiefly illegal fentanyl and heroin, or other illegal drugs that Defendants have never dispensed.

Plaintiffs' evidence at trial was consistent with their opening statement. Although a witness mentioned ongoing prescription opioid abuse, Dkt. 4050 at 2795–96 (Oct. 19 trial tr., vol. 11), he could not link it to any of the pharmacies, *id.* at 2796–97, and the bulk of Plaintiffs' evidence of ongoing abuse focused on illicit drugs. *See* Dkt. 4065 at 3643–45 (Oct. 22 trial tr., vol. 14) (Dr. Keyes explaining the three phases of "opioid epidemic," with prescription opioids as the chief source in the late 1990s and early 2000s, then a shift around 2010 toward heroin, and another shift in 2014 or 2015 to synthetic opioids including fentanyl); Dkt. 4050 at 2762–65 (Oct. 19 trial tr., vol. 11) (noting current problems with illicit fentanyl, cocaine, heroin, methamphetamine, and counterfeit pills, as well as prescription opioids); *id.* at 2792–94; Dkt. 4065

at 3687–88 (Oct. 22 trial tr., vol. 14) (discussing the effects of illicit fentanyl). Although Plaintiffs contend that some prescriptions bore "red flags" into 2019, the bulk of their evidence of alleged improperly filled prescriptions occurred before 2014. *See* Dkt. 4026 at 2108–09 (Oct. 14 trial tr., vol. 8).

Plaintiffs' evidence is intended to show, however implausibly, that they continue to incur *damages* from Defendants' conduct that ended years ago—that is, the prescription-opioid abuse led to illegal-narcotic abuse, and that illegal-narcotic abuse continues to cause damage to the counties when addicted persons put a strain on municipal services. But the principal drugs causing the current alleged damages are not dispensed by Defendants, and no evidence suggests that wrongfully dispensed prescription opioids are currently causing those damages. *See, e.g.*, Dkt. 4118 at 5942–44 (Dr. Murphy discrediting the "gateway" thesis). The evidence presented at trial did not show any continuing misconduct by Defendants and thus it cannot show a continuing public nuisance.[3]

Finally, Plaintiffs may not rely on any sort of tolling. This Court has established that equitable tolling does not apply. *See In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4194296, at *10–12 (N.D. Ohio Sept. 4, 2019) (rejecting equitable tolling). Neither does discovery-rule tolling apply to these kinds of claims, *see Invs. REIT One v. Jacobs*, 546 N.E.2d 206, 210 (Ohio 1989), nor would it provide relief anyway, *see Flowers v. Walker*, 589 N.E.2d 1284, 1287–88 (Ohio 1992). And, likewise, there is no evidence of fraudulent concealment, *see, e.g.*, *Perkins v. Falke & Dunphy, LLC*, 2012-Ohio-5799, 2012 WL 6097104, at *3 (Ohio Ct. App.

[3] Plaintiffs have no right to abatement as a remedy. Plaintiffs' evidence suggests that the alleged nuisance at issue—an ostensible "oversupply" of prescription opioids by Defendants—has been abated; i.e., Defendants' alleged misconduct has terminated, even if Plaintiffs' claimed damages from that misconduct continue to be incurred.

2012), and it would not bar the claims anyway, *Lutz v. Chesapeake Appalachia, L.L.C.*, 717 F.3d 459, 475 (6th Cir. 2013); *see* Dkt. 1874 at 8–14.

In sum, Plaintiffs' claims accrued, and the limitations period began to run, when the allegedly wrongful conduct occurred (i.e., when the alleged illegitimate prescriptions were filled). *LGR Realty, Inc. v. Frank & London Ins. Agency*, 98 N.E.3d 241, 245 (Ohio 2018). The evidence Plaintiffs have introduced shows that all allegedly unlawful or intentional conduct that supposedly caused the nuisance occurred more than four years before the suits, which were filed on December 1 and December 11, 2017. Plaintiffs' claims are thus time-barred.

6. *No Ongoing Nuisance of Prescription Opioids Requiring Abatement.* Plaintiffs have failed to show, as they must, an *ongoing* public nuisance. As explained above, at most Plaintiffs have purported to show a current *illicit* opioid crisis, but their own evidence shows that Defendants only ever dispensed FDA-approved prescription opioids. *See, e.g.*, Dkt. 4005 at 796 (Lembke testimony, Oct. 7 trial tr., vol. 4) ("Q. And you understand that the FDA has approved prescription opioid medicines? A. Yes"); Dkt. 4023 at 1723 (Rannazzisi testimony, Oct. 13 trial tr., vol. 7) ("Q. And in your testimony today, you have no evidence . . . that Walmart distributed prescription opioid medications in Lake or Trumbull Counties that were not approved by the FDA, are you? A. No, sir"); *see also* Dkt. 4090 at 4153 (Dr. Keyes testimony, Oct. 26 trial tr., vol. 16) (Dr. Keyes testifying that if the FDA had not approved 21 different opioids, the opioid crisis would not exist). Plaintiffs argue that Defendants engaged in misconduct as to those prescription medications, and they claim that they continue to incur damages as a result of that misconduct. But that is different from saying that a *prescription opioid* nuisance is ongoing, and Plaintiffs have not made that showing.

7. *Improper Expert Testimony.* Defendants preserve their objection to the admission of expert testimony from Dr. Caleb Alexander (Dkt. 3856-4), Carmen Catizone (Dkt. 3914-2), Dr. Katherine Keyes (Dkt. 3858-2), Dr. Anna Lembke (Dkt. 3915-2), and Craig McCann (Dkt. 3866-2). *See also* Dkt. 3794 (preserving prior expert testimony objections). Without any one of their testimony, Plaintiffs' case is legally insufficient and fails as a matter of law. Among other objections, Defendants renew the following arguments:

- Dr. Alexander's expert opinions were primarily about abatement, which is only relevant at the remedial stage of this trial, Phase Two. Dkt 3856-4 at 3; *see* Dkt. 4064 at 3533–37 (Oct. 21 trial tr., vol. 13) (Alexander testifying and explaining that to remediate the opioid crisis there must be: (1) an improvement in doctors' prescribing practices; (2) removal of unwanted medicine sitting in medicine cabinets; (3) reduction of opioids for nonmedical use; (4) decrease of dangerous combination of medicines; and (5) access to treatment medicines, like Buprenorphine to addicted individuals).

- Catizone's attempt to mechanically identify "red flags" was unreliable, and he has made no attempt to test whether it actually identifies prescriptions that are likely illegitimate and/or likely to be diverted. Dkt. 3914-2 at 1; *see, e.g.*, Dkt. 4017 at 1335, 1337, 1359–60, 1374–76 (Oct. 12 trial tr., vol. 6) (Catizone testifying that when he analyzed the 2,000 prescription data, he made no attempt to identify and determine: (1) patients who needed to fill their prescriptions close to work versus where they lived; (2) patients who actually had insurance when they paid in cash; (3) the type of doctor prescribing the medication; and (4) the historical prescription data-monitoring systems and policies available to Defendants); *id.* at 1402 (Catizone further admitting that he did not apply the Government or DEA metrics in his analysis to determine the percentage of the medicines pharmacies dispensed to determine controlled substances versus no controlled substances and regular prescriptions).

- Dr. Keyes' causation opinions were not based on peer-reviewed literature, and have not been scientifically tested in any way. They are solely the product of Dr. Keyes' unsound reasoning, not any reliable scientific methodology. Dkt. 3858-2 at 1; *see, e.g.*, Dkt. 4090 at 4120–21 (Oct. 26 trial tr., vol. 16) (discounting Keyes' findings that the percentage of modern heroin users that started with prescription opioid use in the 2000s was 75%, by analyzing the Cicero paper, which concluded that heroin use as an initiating opioid grew sharply from 8.7% in 2005 to 31.6% in 2015); *id.* at 4134–35 (discounting Keyes conclusion about how addiction to heroin starts with the use of a prescription opioid, by discussing the Muhuri study, which demonstrated that 97.7% of people who started heroin have used other illicit drugs besides prescription opioid pills before starting heroin).

- Dr. Lembke offered opinions far beyond her expertise and qualifications. Despite disclaiming any knowledge or expertise on the practice of pharmacy (and admittedly never having practiced, studied, or worked in a pharmacy), she offered expert opinions about pharmacies' national policies and dispensing practices. Dkt. 3915-2 at 1; *see, e.g.*, Dkt. 4000 at 636–37, 540–41 (Oct. 6 trial tr., vol. 3) (Dr. Lembke testifying that: (1) Defendants' policies and procedures were not effective or adequate to detect red flags; and (2) Defendants increased the supply of opioids and failed to provide effective controls against diversion, which led to opioid misuse and addiction).
- McCann offered no opinions about the validity of any of the criteria Plaintiffs' lawyers told him to use or the appropriateness of any of the dispensing transactions he flagged, relying entirely on counsel and other experts to make those determinations. His opinions were thus inherently arbitrary and unreliable. Dkt. 3866-2 at 1–2; *see* Dkt. 4032 at 2255, 2262–64 (Oct. 15 trial tr., vol. 9) (McCann testifying that he programmed algorithms that reflected flagging rules suggested by Plaintiffs' counsel and Catizone, and that the algorithms did not differentiate, among other things, between primary care physicians and specialists, between patients with chronic pain and patients who underwent various treatments, and between short-acting opioids and long-acting opioids).

CONCLUSION

For these reasons, the Court should grant judgment as a matter of law under Rule 50(b) in favor of Defendants.

Dated: December 21, 2021

Respectfully submitted,

/s/ John M. Majoras
John M. Majoras
Benjamin C. Mizer
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
Phone: (202) 879-3939
Fax: (202) 626-1700
E-mail: jmmajoras@jonesday.com
E-mail: bmizer@jonesday.com

Tina M. Tabacchi
Tara A. Fumerton
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
Fax: (312) 782-8585
E-mail: tmtabacchi@jonesday.com
E-mail: tfumerton@jonesday.com

Counsel for Walmart Inc.

/s/ Eric R. Delinsky
Eric R. Delinsky
Alexandra W. Miller
Graeme W. Bush
Paul B. Hynes, Jr.
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
E-mail: edelinsky@zuckerman.com
E-mail: smiller@zuckerman.com
E-mail: gbush@zucerkman.com
E-mail: phynes@zuckerman.com

Counsel for CVS Pharmacy, Inc., Ohio CVS Stores, L.L.C., CVS TN Distribution, L.L.C., CVS Rx Services, Inc., and CVS Indiana, L.L.C.

/s/ Kaspar J. Stoffelmayr
Kaspar J. Stoffelmayr
Brian C. Swanson
Katherine M. Swift
Sharon Desh
Sten Jernudd
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, IL 60654
Tel: (312) 494-4400
Fax: (312) 494-4440
kaspar.stoffelmayr@bartlitbeck.com
brian.swanson@bartlitbeck.com
kate.swift@bartlitbeck.com
sharon.desh@bartlitbeck.com
sten.jernudd@bartlitbeck.com

Alex J. Harris
BARTLIT BECK LLP
1801 Wewatta Street, 12th Floor
Denver, CO 80202
Tel: (303) 592-3100
Fax: (303) 592-3140
alex.harris@bartlitbeck.com

Counsel for Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system on all counsel of record on December 21, 2021.

/s/ John M. Majoras
John M. Majoras
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
Phone: (202) 879-3939
Fax: (202) 626-1700
E-mail: jmmajoras@jonesday.com

Counsel for Walmart Inc.